

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION and  
THE PEOPLE OF THE STATE OF NEW  
YORK, by LETITIA JAMES, Attorney  
General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING  
COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited  
liability company;

PREVAGEN, INC., a corporation  
d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE  
MANUFACTURING, LLC, a limited  
liability company; and

MARK UNDERWOOD, individually and as  
an officer of QUINCY BIOSCIENCE  
HOLDING COMPANY, INC., QUINCY  
BIOSCIENCE, LLC, and PREVAGEN,  
INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

**QUINCY'S PROPOSED JURY INSTRUCTIONS  
AND REQUESTS TO CHARGE**

Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC (collectively, "Quincy") respectfully submit the following Jury Instructions and Requests to Charge. Quincy reserves the right to propose additional instructions or to amend or delete any of the instructions attached hereto at any time before the instructions are given to the jury.

Dated: January 12, 2024  
New York, New York

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## GENERAL INSTRUCTIONS

### 1. Role of the Court

You have now heard all of the evidence in the case as well as the final arguments of the lawyers for the parties.

My duty at this point is to instruct you as to the law. It is your duty to accept these instructions of law and apply them to the facts as you determine them, just as it has been my duty to preside over the trial and decide what testimony and evidence is relevant under the law for your consideration.

On these legal matters, you must take the law as I give it to you. If any attorney has stated a legal principle different from any that I state to you in my instructions, it is my instructions that you must follow.

You should not single out any instruction as alone stating the law, but you should consider my instructions as a whole when you retire to deliberate in the jury room.

You should not be concerned about the wisdom of any rule that I state. Regardless of any opinion that you may have as to what the law may be—or ought to be—it would violate your sworn duty to base a verdict upon any view of the law other than that which I give you.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Modern Federal Jury Instructions, Instruction 71-2 (2022) (hereinafter referred to as “Sand, Siffert, Laughlin, Reiss, Allen, Rakoff”).

## **2. Role of the Jury**

As members of the jury, you are the sole and exclusive judges of the facts. You pass upon the evidence. You determine the credibility of the witnesses. You resolve such conflicts as there may be in the testimony. You draw whatever reasonable inferences you decide to draw from the facts as you have determined them, and you determine the weight of the evidence.

In determining these issues, no one may invade your province or functions as jurors. In order for you to determine the facts, you must rely upon your own recollection of the evidence. What the lawyers have said in their opening statements, in their closing arguments, in their objections, or in their questions is not evidence. Nor is what I may have said during the trial—or what I may say in these instructions—evidence. You should bear in mind that a question put to a witness is never evidence, it is only the answer that is evidence. But you may not consider any answer that I directed you to disregard or that I directed struck from the record. Such answers are not evidence and may not be considered.

Because you are the exclusive judges of the facts, I do not mean to indicate any opinion as to the facts or what your verdict should be. The rulings that I made during the trial are not any indication of my views of what your decision should be as to whether or not the plaintiff has proven its case.

I also ask that you draw no inference from the fact that upon occasion I asked questions of certain witnesses. These questions were only intended for clarification or to expedite matters and certainly were not intended to suggest any opinions on my part as to the verdict that you should render, or whether any of the witnesses may have been more credible than any other witnesses. You are to understand that the court has no opinion as to the verdict you should render in this case.

As to the facts, you are the exclusive judges. You are to perform the duty of finding the

facts without bias or prejudice to any party.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 71-3.

### **3. Conduct of Counsel**

It is the duty of the attorney on each side of a case to object when the other side offers testimony or other evidence that the attorney believes is not properly admissible. Counsel also has the right and duty to ask the court to make rulings of law and to request conferences at the side bar out of the hearing of the jury. All those questions of law must be decided by me, the court. You should not show any prejudice against an attorney or his client because the attorney objected to the admissibility of evidence, or asked for a conference out of the hearing of the jury or asked the court for a ruling on the law.

As I already indicated, any rulings on the admissibility of evidence do not, unless expressly stated by me, indicate any opinion as to the weight or effect of such evidence. You are the sole judges of the credibility of all witnesses and the weight and effect of all evidence.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 71-6.

#### **4. Common Counsel and Counsel Cooperation**

Although some of the defendants in this trial are being represented by the same counsel, you are not to treat them as one person. Each defendant is entitled to your separate consideration. The question of whether liability has been proven is personal to each defendant and must be decided by you as to each defendant individually.

You may have noticed throughout the trial that counsel for various defendants have consulted with each other and have divided the work of the trial in an effort to facilitate their presentation and to avoid duplication. This does not mean that the defendants' cases are to be viewed together. Again, the issue of each defendant's liability is personal and must be decided by you as to each defendant individually.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 71-8.

## **5. Publicity**

There may be some media attention given to this case, or there may be some talk about it on the radio, television, or internet. If there is media attention during the trial, you must insulate yourselves from all information about this case, except what comes to you in this courtroom through the rules of evidence. So, when you leave here and go to your home and pick up the paper or look at social media, if you see something about the case, you must stop right away. Do not read anything about this case.

I will also tell you to avoid listening to or watching any radio or television discussion of the case or the Prevagen Products.

Your verdict must be based solely on the evidence presented in this courtroom in accordance with my instructions. You must completely disregard any report that you have read in the press, seen on television, heard on the radio, or read on the internet. It would be unfair to consider such reports, since they are not evidence and the parties have no opportunity to contradict their accuracy or otherwise explain them away. In short, it would be a violation of your oath as jurors to allow yourselves to be influenced in any manner by such publicity.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instructions 71-12; 71-14.



## **6. Note-Taking by Jury**

If you want to take notes during the course of the trial, you may do so. If you do take notes, be sure that your note-taking does not interfere with your listening to and considering all of the evidence. Also, if you take notes, do not discuss them with anyone before or during your deliberations. Your notes are to be used solely to assist you and are not to substitute for your recollection of the evidence in the case. The fact that a particular juror has taken notes entitles that juror's views to no greater weight than those of any other juror and your notes are not to be shown to any other juror during your deliberations. If, during your deliberations, you have any doubt as to any of the testimony, you will be permitted to request that the official trial transcript which is being made of these proceedings be read to you.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instructions 71-16.

## **7. Burden of Proof**

You are being asked to decide certain claims brought in this action by Plaintiff the New York Attorney General. I will explain those claims to you shortly. In the meantime, you should be aware that the NYAG has the burden of proving every disputed element of its claims to you by a preponderance of the evidence. If you conclude that the NYAG has failed to establish any of its claims by a preponderance of the evidence, you must decide against the NYAG on the claim you are considering.

To establish a fact by a preponderance of the evidence means to prove that the fact is more likely true than not true. A preponderance of the evidence means the greater weight of the evidence. It refers to the quality and persuasiveness of the evidence, not the number of witnesses or documents. In determining whether a claim has been proven by a preponderance of the evidence, you may consider the relevant testimony of all witnesses regardless of who may have called them, and all the relevant exhibits received in evidence, regardless of who may have introduced them.

If you find that the credible evidence on a given issue is evenly divided between the parties—that it is equally probable that one side is right as it is that the other side is right—then you must decide that issue against the NYAG. That is because the NYAG must prove more than simple equality of evidence—it must prove the element at issue by a preponderance of the evidence.

Some of you may have heard of proof beyond a reasonable doubt, which is the proper standard of proof in a criminal trial. That requirement does not apply to a civil case such as this and you should put it out of your mind.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 73-2; *Fischl v. Armitage*, 128 F.3d 50 (2d Cir. 1997); *Larson v. JoAnn Cab Corp.*, 209 F.2d 929, 935 (2d Cir. 1954).

## **8. Consideration of the Evidence—What is and is Not Evidence**

The evidence in this case is the sworn testimony of the witnesses, the exhibits received in evidence, stipulations, and judicially noticed facts.

By contrast, the questions of the lawyers are not to be considered by you as evidence. It is the witnesses' answers that are evidence, not the questions. At times, a lawyer may incorporate into a question a statement which assumes certain facts to be true, and ask the witness if the statement is true. If the witness denies the truth of a statement, and if there is no direct evidence in the record proving that assumed fact to be true, then you may not consider it to be true simply because it was contained in the lawyer's question.

Testimony that has been stricken or excluded is not evidence and may not be considered by you in rendering your verdict. Also, if certain testimony was received for a limited purpose—such as for the purpose of assessing a witness's credibility—you must follow the limiting instructions I have given.

Arguments by lawyers are not evidence, because the lawyers are not witnesses. What they have said to you in their opening statements and in their summations is intended to help you understand the evidence to reach your verdict. However, if your recollection of the facts differs from the lawyers' statements, it is your recollection that controls.

Exhibits that were marked for identification may not be considered by you as evidence unless they were received in evidence by the court. To constitute evidence, exhibits must be received in evidence. Exhibits marked for identification but not admitted are not evidence, nor are materials brought forth only to refresh a witness' recollection.

Finally, statements that I may have made concerning the quality of evidence do not constitute evidence.

It is for you alone to decide the weight, if any, to be given to the testimony you have heard and the exhibits that you have seen.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 74-1.

## **9. Consideration of Evidence—Direct and Circumstantial Evidence**

There are two types of evidence that you may properly use in reaching your verdict.

One type of evidence is direct evidence. Direct evidence is when witnesses testify about something they know by virtue of their own senses—something they have seen, felt, touched, or heard. Direct evidence may also be in the form of an exhibit when the fact to be proved is its present existence or condition.

The other type of evidence is circumstantial evidence. This is evidence that tends to prove a disputed fact by proof of other facts. There is a simple example of circumstantial evidence that is often used in this courthouse.

Assume that when you came into the courthouse this morning the sun was shining and it was a nice day. Assume that the courtroom blinds were drawn and you could not look outside. As you were sitting here, someone walked in with an umbrella which was dripping wet. Then a few minutes later another person also entered with a wet umbrella. Now, you cannot look outside of the courtroom and you cannot see whether or not it is raining. So you have no direct evidence of that fact. But on the combination of facts which I have asked you to assume, it would be reasonable and logical for you to conclude that it had been raining.

That is all there is to circumstantial evidence. You infer on the basis of reason and experience and common sense from one established fact the existence or non-existence of some other fact.

Circumstantial evidence is of no less value than direct evidence. It is a general rule that the law makes no distinction between direct evidence and circumstantial evidence but simply requires that your verdict must be based on (e.g., a preponderance of) all the evidence presented.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 74-2.

## **10. Interrogatories**

Some of the evidence before you is in the form of interrogatories. Interrogatories are written questions posed by one side that call for written answers under oath from the other side. Both the questions and answers are made prior to trial after the case has begun in what is called pretrial discovery, and each side is entitled to seek such discovery from the other.

You may consider a party's answers to interrogatories as evidence against a party who made the answer, just as you would any other evidence that has been admitted in this case.

In this regard, you are not required to consider a party's answers to interrogatories as true, nor are you required to give them more weight than any other evidence. It is up to you to determine what weight, if any, should be given to the interrogatory answers that have been admitted as evidence.

One cautionary word on this subject: while you may consider the interrogatory answers as evidence for or against the party who gave the answers, you may not consider the answers for or against any other party, nor may you consider the answers as evidence for or against the party who posed the interrogatory questions. You may only consider the interrogatory answer as evidence for or against the party who gave the answer.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 74-13.



## **11. Deposition Testimony**

Some of the testimony before you is in the form of depositions that have been received in evidence. A deposition is simply a procedure where prior to trial the attorneys for one side may question a witness or an adverse party under oath before a court stenographer and videographer. This is part of the pretrial discovery, and each side is entitled to take depositions. You may consider the testimony of a witness given at a deposition according to the same standards you would use to evaluate the testimony of a witness given at trial.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 74-14.

### **13. Stipulated Facts**

Some of the evidence before you is in the form of stipulated facts. Before the trial of this case, the parties both submitted proposed findings of facts to the Court that they believed would sustain a verdict in their favor. For certain of those facts, the parties agreed that the facts could be taken as true without further proof. Because the parties have stipulated to these facts and do not dispute them, you are to take these facts as true for purposes of this case.

Authority: Dkt. 299 (Pretrial Order).

#### **14. Requests for Admission**

Some of the evidence before you is in the form of requests for admission. Requests for admission are written statements of fact submitted by one party prior to trial to the opposing party. The opposing party has a certain amount of time in which to respond to the requests, knowing that the failure to respond within that time will be deemed equivalent to admitting the truth of the statements contained in the requests.

If a party admitted or failed to respond to a request for admission, the requests admitted in evidence are binding and conclusive on that party for the purposes of this trial.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 74-15.

## **15. Credibility of Witnesses**

You have had the opportunity to observe all the witnesses and consider their testimony. It is now your job to decide how believable the witnesses were in their testimony. You are the sole judges of the credibility of each witness and of the importance of his testimony.

It must be clear to you by now that you are being called upon to resolve various factual issues raised by the parties in the face of very different pictures painted by both sides. In making these judgments, you should carefully scrutinize all of the testimony of each witness, the circumstances under which each witness testified, and any other matter in evidence which may help you decide the truth and the importance of each witness' testimony.

How do you determine where the truth lies? You watched each witness testify. Everything a witness said or did on the witness stand counts in your determination. How did the witnesses impress you? Did they appear to be frank, forthright and candid, or evasive and edgy as if hiding something? How did the witnesses appear? What was their demeanor—that is, their carriage, behavior, bearing, manner, and appearance while testifying? Often it is not what witnesses say but how they say it that moves us.

You should use all the tests for truthfulness that you would use in determining matters of importance to you in your everyday life. You should consider any bias or hostility the witnesses may have shown for or against any party as well as any interest the witnesses have in the outcome of the case. You should consider the opportunity the witnesses had to see, hear, and know the things about which they testified, the accuracy of their memory, their candor or lack of candor, their intelligence, the reasonableness and probability of their testimony and its consistency or lack of consistency and its corroboration or lack of corroboration with other credible testimony.

In other words, what you must try to do in deciding credibility is to size the witnesses up

in light of their demeanor, the explanations given and all of the other evidence in the case. Always remember that you should use your common sense, your good judgment and your own life experience.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 76-1.

## **16. Duty to Deliberate**

You must deliberate with your fellow jurors to decide the issues in this case. To decide in favor of the NYAG, you must decide that it has sustained its burden of proof as I have explained to you with respect to each element of its claims (which I will detail for you shortly). If you find that the NYAG failed to sustain its burden on any element of its claims, you should return a verdict against the NYAG and in favor of Quincy.

It is your duty as jurors to consult with one another and to deliberate with a view to reaching an agreement. Each of you must decide the case for yourself, but you should do so only after a consideration of the case with your fellow jurors, and you should not hesitate to change an opinion when convinced that it is erroneous. Your verdict must be unanimous, but you are not bound to surrender your honest convictions concerning the effect or weight of the evidence for the mere purpose of returning a verdict or solely because of the opinion of other jurors. Discuss and weigh your respective opinions dispassionately, without regard to sympathy, without regard to prejudice or favor for any party, and adopt that conclusion which in your good conscience appears to be in accordance with the truth.

Again, each of you must make your own decision about the proper outcome of this case based on your consideration of the evidence and your discussions with your fellow jurors. Jurors should not surrender their conscientious beliefs solely for the purpose of returning a unanimous verdict.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 78-3.

### **17. Right to See Exhibits and Hear Testimony During Deliberations**

During your deliberations, if you want to see any of the exhibits, you may request that they be brought into the jury room. If you want any of the testimony read back to you, you may also request that. Please remember that it is not always easy to locate what you might want, so be as specific as you possibly can in requesting exhibits or portions of the testimony.

Your requests for exhibits or testimony—in fact any communication with the court—should be made to me in writing, signed by your foreperson, and given to one of the marshals. In any event, do not tell me or anyone else how the jury stands on any issue until after a unanimous verdict is reached.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 78-1.

## **18. Expert Witnesses**

In this case, I have permitted certain witnesses to express their opinions about matters that are in issue. Witnesses may be permitted to testify to opinions on those matters about which they have special knowledge, skill, experience, and training. Such testimony is presented to you on the theory that someone who is experienced and knowledgeable in the field can assist you in understanding the evidence or in reaching an independent decision on the facts.

To the extent that the testimony of an expert witness who testified in this case is in conflict with the testimony of another expert witness, you are charged with resolving that conflict. You are the sole trier of the facts and must determine any questions of fact raised by conflicting expert testimony just as you are charged with resolving questions of fact raised by any other conflicting evidence in this case.

In weighing this opinion testimony, you may consider the witnesses' qualifications, their opinions, the reasons for testifying, as well as all of the other considerations that ordinarily apply when you are deciding whether or not to believe a witness's testimony. You may give the opinion testimony whatever weight, if any, you find it deserves in light of all the evidence in this case. You should not, however, accept opinion testimony merely because I allowed the witness to testify. Nor should you substitute it for your own reason, judgment, and common sense. The determination of the facts in this case rests solely with you.

Authority: Sand, Siffert, Loughlin, Reiss, Allen, Rakoff, Instruction 76-9, 76-10.



### 19. The NYAG's Claims Before the Jury

The NYAG is bringing claims against Quincy under New York's General Business Law and New York's Executive Law, both New York statutes. I will refer to the General Business Law as the "GBL." The NYAG is seeking to force Quincy to pay monetary restitution and civil penalties under the GBL.

You will be deciding whether the NYAG has proven that Quincy violated the GBL and whether the NYAG is entitled to force Quincy to pay restitution and/or civil penalties. Or, put differently, you will be deciding whether the NYAG has established Quincy's liability under the GBL by establishing that the challenged advertising is materially misleading because it is false, misleading, or unsubstantiated. The Court will determine the amount of restitution and civil penalties to be paid by Quincy, if any.

Authority: § 2302.1 Judicial Construction of the Jury Trial Guarantee, 9 Fed. Prac. & Proc. Civ. § 2302.1 (4th ed.); *Wade v. Orange County Sheriff's Office*, 844 F.2d 951, 954-55 (2d Cir. 1988); *Song v. Ives Laboratories, Inc.*, 957 F.2d 1041, 1048 (2d Cir. 1992); *City of New York v. FedEx Ground Package Sys., Inc.*, No. 13 CIV. 9173 (ER), 2018 WL 4961455, at \*7 (S.D.N.Y. Oct. 15, 2018); *United States v. Acquest Transit LLC*, No. 09-CV-55S, 2021 WL 809984, at \*11 (W.D.N.Y. Mar. 3, 2021).

## **20. General Business Law Section 349 and Section 350 – Elements**

The NYAG's claims under Section 349 and Section 350 of the GBL relate to Quincy's marketing of Prevagen. You will decide whether the NYAG has proven its claims that Quincy violated those sections of the GBL.

The elements of claims under Section 349 and Section 350 of the GBL are substantially the same.

GBL Section 349 prohibits "deceptive acts and practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." In order for the NYAG to prove its claim for a violation of Section 349 of the GBL, you must find that the NYAG has proven two elements by a preponderance of the evidence: (1) that Quincy committed a deceptive act or practice that was consumer oriented; (2) and that the deceptive act or practice was misleading in a material way.

GBL Section 350 prohibits "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state." In order for the NYAG to prove its claim for a violation of Section 350 of the GBL, you must find that the NYAG has proven two elements by a preponderance of the evidence: (1) that an advertisement disseminated by Quincy had an impact on consumers at large, and (2) that an advertisement disseminated by Quincy was deceptive or misleading in a material way.

The NYAG must prove each and every element of its claims under Section 349 and Section 350 of the GBL as to each defendant by a preponderance of the evidence. If you find that the NYAG failed to carry its burden on any one of those elements with regard to any one of the defendants, you must find in favor of that defendant and against the NYAG. You are in no way obligated to find that the NYAG has carried its burden on any element with regard to a particular

defendant simply because you find that it has carried that burden with regard to another defendant.

Authority: New York Pattern Jury Instruction 3:20; *Gristede's Foods, Inc. v. Unkechauge Nation*, 532 F. Supp. 2d 439, 450-51 (E.D.N.Y. 2007); *Goshen v. Mut. Life Ins. Co. of New York*, 98 N.Y.2d 314, 324 n.1 (2002).

**21. General Business Law Section 349 and Section 350 – “Consumer Oriented”**

A claim under either Section 349 or Section 350 of the GBL must be predicated on a deceptive act, practice, or advertisement that is consumer oriented as distinguished from merely a private contractual dispute. Recurring conduct is not required, but the NYAG must show that the complained-of acts or practices had a broad impact on consumers at large.

Authority: New York Pattern Jury Instruction 3:20.

## **22. General Business Law Section 349 and Section 350 – “Deceptive”**

The NYAG must prove that Quincy’s alleged acts, practices, or advertisements were deceptive. An act, practice, or advertisement is deceptive when it is likely to mislead a reasonable consumer acting reasonably under the circumstances.

Under the “reasonable consumer” standard, the NYAG must prove that Quincy’s statements were, in fact, conveyed to a significant portion of the general consuming public acting reasonably in the circumstances. The reasonable-consumer standard is an objective one. And the reasonable-consumer standard requires more than a mere possibility that Quincy’s marketing might conceivably be misunderstood by a few consumers viewing it in an unreasonable manner. The reasonable-consumer standard instead requires a probability that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.

Authority: New York Pattern Jury Instruction 3:20; *In re: KIND LLC “Healthy and All Natural” Litig.*, Civ. Act. Nos. 15-MD-2645 (NRM), 15-MC-2645 (NRB), 2022 WL 4125065, \*7 (S.D.N.Y. Sept. 9, 2022); *Hughes v. Ester C Co.*, 330 F. Supp. 3d 862, 871 (E.D.N.Y. 2018).

### **23. General Business Law Section 349 and Section 350 – Implied or Express Marketing Claims**

In assessing whether Quincy's advertisements for Prevagen were misleading, you must decide what marketing claims Quincy actually made in the challenged advertisements. In doing so, you should consider whether Quincy's advertisements made express or implied marketing claims about Prevagen. A claim is express if it is not susceptible to more than one reasonable interpretation. A claim is implied if it is susceptible to more than one reasonable interpretation.

If a marketing claim is implied, you need not conclude that the advertisement, in fact, conveys the marketing claim that the NYAG alleges in the absence of any extrinsic evidence showing that a significant portion of consumers interpreted the advertisement to make that claim. To illustrate, consider a food product advertised to be "All Natural." Because the phrase "All Natural" is susceptible to more than one reasonable interpretation (the product could be organic, pesticide-free, unadulterated, etc...), the plaintiff would be required to introduce extrinsic evidence demonstrating a reasonable consumer's understanding of the phrase "All Natural." That evidence can take the form of a consumer survey or other evidence of consumer perception. In the absence of such consumer-perception evidence, you would not be required to accept the plaintiff's proposed interpretation of "All Natural."

If you find that Quincy made implied marketing claims in advertisements for Prevagen, and if you find that the NYAG has not produced evidence showing whether a reasonable consumer would interpret those advertisements in the manner alleged by the NYAG, you must find in favor of Quincy with respect to those marketing claims.

Authority: *FTC v. Alcoholism Cure Corp.* No. 3:10-CV-00266, 2011 WL 13137951, at \*25 (M.D.

Fla. Sept. 16, 2011); *FTC v. Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008); *In re: KIND LLC "Healthy and All Natural" Litig.*, Civ. Act. Nos. 15-MD-2645 (NRM), 15-MC-2645 (NRB), 2022 WL 4125065, \*7 (S.D.N.Y. Sept. 9, 2022); *Hughes v. Ester C Co.*, 330 F. Supp. 3d 862, 871 (E.D.N.Y. 2018); *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 525 (S.D.N.Y. 2009).

**24. General Business Law Section 349 and Section 350 – Disclaimers**

In deciding what marketing claims Quincy conveyed in its advertisements for Prevagen, the primary piece of evidence that you should consider is the advertisements themselves. You should also consider the context in which the advertisement or representation appeared. For example, under certain circumstances, the presence of a disclaimer or similar clarifying language may defeat a claim of deception because, when the full marketing claim is considered, the marketing claim that was actually conveyed is not the one that the plaintiff alleged was made. Clear disclaimers therefore inform the inquiry into whether a reasonable consumer would be misled by the defendant's conduct. In evaluating the efficacy of such a disclaimer, you should consider factors such as the wording, font size, placement, and emphasis of the disclaimer.

Authority: New York Pattern Jury Instruction 3:20; *Bowring v. Sapporo U.S.A., Inc.*, 234 F. Supp. 3d 386, 390 (E.D.N.Y. 2017); *Fink v. Time Warner Cable*, 714 F.3d 739, 742 (2d Cir. 2013); *Delgado v. Ocwen Loan Servicing, LLC*, No. 13-CV-4427, 2014 WL 4773991, at \*8 (E.D.N.Y. Sept. 24, 2014).



**25. General Business Law Section 349 and Section 350 – Compliance with Federal Standards is a Complete Defense**

Section 349 and Section 350 of the GBL are both modeled on the analogous Federal Trade Commission Act. Sections 349 and 350 were enacted to follow the FTC’s direction with respect to what practices and acts were either accepted or prohibited under the FTC Act. Both Section 349 and Section 350 of the GBL therefore provide that if the challenged act or practice or advertisement complies with the rules and regulations of the Federal Trade Commission or any other federal agency, such as the Food and Drug Administration (“FDA”), it is a complete defense to any claims brought under those sections.

Authority: GBL Section 349(d); GBL Section 350-d; *Braynina v. TJX Companies, Inc.*, No. 15 CIV. 5897 (KPF), 2016 WL 5374134, at \*6 (S.D.N.Y. Sept. 26, 2016); *State by Lefkowitz v. Colo. State Christian Coll. of Church of Inner Power, Inc.*, 346 N.Y.S.2d 482, 487 (N.Y. Sup. Ct. 1973).

## 26. DSHEA and Structure-Function Claims

Federal law, which the NYAG has acknowledged governs its claims under the GBL, regulates dietary supplements. In 1994, Congress passed the Dietary Supplement Health and Education Act (“DSHEA”), providing the FDA with regulatory authority over dietary supplements. DSHEA explained what statements dietary supplement manufacturers could make in conjunction with their products and what statements had to be approved by the FDA prior to their use. In particular, DSHEA and regulations promulgated by the FDA distinguish between “structure/function” claims and “disease claims” for dietary supplements. A structure/function claim is one that:

claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.

21 U.S.C. § 343(r)(6)(A); 21 C.F.R. § 101.93(f). Examples of “structure/function” claims include claims that a dietary supplement will benefit those with “mild memory loss associated with aging,” “noncystic acne,” or “mild mood changes, cramps, and edema associated with the menstrual cycle.” Whereas, on the other hand, examples of disease claims include a representation that a dietary supplement will “treat,” “correct,” “prevent,” a specific disease such as “Alzheimer’s disease or senile dementias in the elderly,” “cystic acne,” or “severe depression associated with the menstrual cycle.”

The distinction between “structure/function” claims and “disease” claims matters because “structure/function” claims are not required to be approved by the FDA. A marketer may make “structure function” marketing claims in labeling if it notifies the FDA that it intends to make the

claim and includes a disclaimer that the claim has not been evaluated by FDA and that the product is not intended to diagnose, mitigate, treat, cure, or prevent any disease. DSHEA also requires “structure/function” claims in labeling be substantiated and be truthful and not misleading. A more stringent standard is applied to disease claims. Those claims are permitted only if they have been authorized by an FDA finding that there is “significant scientific agreement” to support the claim. The NYAG is not arguing that any of the challenged marketing claims for Prevagen constitute disease claims. In other words, the NYAG is not alleging that Quincy improperly marketed Prevagen as a drug.

Authority: 21 U.S.C. § 343(r)(6); *Gallagher v. Bayer AG*, No. 14-CV-04601-WHO, 2015 WL 1056480, at \*3-4 (N.D. Cal. Mar. 10, 2015); Food and Drug Administration, Small Entity Compliance Guide on Structure/Function Claims (Jan. 2002); *Dietary Supplements: An Advertising Guide for Industry* (April 2001).

## **27. General Business Law Section 349 and Section 350 – Dietary Supplement Substantiation Standard**

After you have decided what marketing claims Quincy conveyed in its advertisements for Prevagen, you must decide whether those statements were materially misleading. To carry its burden with regard to the materially misleading element of its GBL claims, the NYAG must prove by a preponderance of the evidence that each corporate defendant that made a representation about Prevagen lacked sufficient substantiation for that statement at the time it was made. The FTC issued guidance to the dietary-supplement industry and articulated a standard for how structure/function claims can be adequately substantiated. The FTC set out a “competent and reliable scientific evidence” standard. The NYAG has acknowledged that the “competent and reliable scientific evidence” standard governs its claims in this case under the GBL. And so, to prove that Quincy’s claims lacked sufficient substantiation or were otherwise materially misleading, the NYAG must show that the marketing claims were not supported by “competent and reliable scientific evidence.”

The “competent and reliable scientific evidence” standard is found in *Dietary Supplements: An Advertising Guide for Industry*, which was issued by the FTC in April 2001. I will refer to *Dietary Supplements: An Advertising Guide for Industry* as the “FTC Guidance.” “Competent and reliable scientific evidence” is defined in the FTC Guidance as “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” The FTC Guidance also states that a “guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate.”

The FTC Guidance instructs that “[t]here is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration.” The “competent and reliable scientific evidence” is a flexible standard and considers all forms of scientific evidence, including, the existing scientific literature or scientific studies performed by the defendant. To count as “competent and reliable scientific evidence,” a scientific study need not meet any particular standard and need not be a randomized controlled trial with human subjects. The FTC Guidance states that “although well-controlled human clinical studies are the most reliable form of evidence,” “results obtained in animal and in vitro studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible.”

In deciding whether Quincy has sufficient scientific substantiation for their representations about Prevagen, you should consider all forms of scientific evidence, including human clinical studies, animal studies, in vitro studies, scientific literature, and expert opinion. You may only find in favor of the NYAG on its GBL claims if you find by a preponderance of the evidence that a corporate defendant lacked such “competent and reliable scientific evidence” supporting a representation about Prevagen but made that statement to consumers nonetheless. If you do not find that the NYAG has proven by a preponderance of the evidence that a corporate defendant lacked such substantiation, you must find in favor of that corporate defendant and against the NYAG on its GBL claims.

Authority: *Dietary Supplements: An Advertising Guide for Industry* (April 2001); *United States v. Bayer Corp.*, No. CV 07-01, 2015 WL 5822595, at \*3-4 (D.N.J. Sept. 24, 2015); *Basic Research, LLC v. FTC*, No. 2:09-CV-0779, 2014 WL 12596497, at \*10-11 (D. Utah Nov. 25, 2014).

## **28. New York Executive Law Section 63(12)**

New York Executive Law Section 63(12) allows the NYAG to seek relief for repeated fraudulent or illegal acts or otherwise demonstrated persistent fraud or illegality in the carrying on, conducting or transaction of business. Section 63(12) does not create an independent cause of action but allows the NYAG to show that injunctive and other relief is appropriate if it can show that Quincy violated other statutes.

You can only find that the NYAG is entitled to relief under Executive Law Section 63(12) if you find that the NYAG has proven its claims by a preponderance of the evidence under either GBL Section 349 or Section 350.

Authority: New York Executive Law Section 63(12); *People ex rel. Schneiderman v. One Source Networking, Inc.*, 3 N.Y.S.3d 505, 508 (4th Dep’t 2015).

## **29. Deliberations, Election of Foreperson, and Special Verdict**

I have now outlined for you the law applicable to the NYAG's claims in this case and how you should weigh the evidence and determine the facts. In a few minutes, you will return to the jury room for your deliberations. Upon returning to the jury room, you will select one person to act as your foreperson. The foreperson will preside over your deliberations and will be your spokesperson here in court. In your deliberations, your goal is to reach a fair conclusion from the law and from the evidence. Any verdict that you reach must be unanimous.

Once you are in the jury room, you may then discuss the case. It is, in fact, the duty of each of you to consult with your fellow jurors and to deliberate with a view toward reaching agreement on a verdict, if you can do so without violating your individual judgment and your conscience. In the course of your deliberations, no one should surrender conscientious beliefs of what the truth is and what the weight and effect of the evidence is. Each of you must decide the case for yourself and not merely acquiesce in the conclusion of your fellow jurors.

If, in the course of your deliberations, you wish further help as to the law, or if you wish to hear any further explanation as to the law, you may send me a note telling me what you would like.

Two special verdict forms have been prepared for your convenience. There is a special verdict form for the NYAG's claim for a violation of GBL Section 349 and a special verdict form for the NYAG's claim for a violation of GBL Section 350. You will take these special verdict forms with you to the jury room.

Most of the questions call for a "yes" or "no" answer. The answer to each question must be the unanimous answer of all of the jurors. Your foreperson will write the unanimous answer of the jury in the space provided. As you will see from the wording and instructions on the special verdict forms, it may not be necessary to answer all of the questions in the special verdict forms.

Once you have completed the special verdict forms, the foreperson will then date and sign the special verdicts and you will then return them to the courtroom.